000FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE REV. 2/01T

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER

|   | DES   | IGNA'   | TED/EL  | 09825.0001               |   |   |  |  |  |  |  |  |  |  |
|---|---|---|---|--------------------------|---|---|--|--|--|--|--|--|--|--|
|   |   |   | ING A   | U.S. APPLICATION NO.     |   |   |  |  |  |  |  |  |  |  |
|   |   | . 0214  |   | (If known, see 37CFR1.5) |   |   |  |  |  |  |  |  |  |  |
|   |   |   |   |                          |   | 10/534358                                 |  |  |  |  |  |  |  |  |
| INTER   | RNATION   | AL APPL   | ICATION N   | <b>10</b> .              | INTERNATIONAL FILING DATE                         | PRIORITY DATE CLAIMED                     |  |  |  |  |  |  |  |  |
| PCT/IB2003/004998   |   |   |   |                          | November 3, 2003                                  | November 7, 2002                          |  |  |  |  |  |  |  |  |
| TITLE OF INVENTION: PROCESS FOR PREPARATION OF POLYMORPHIC FORM OF SERTRALINE<br>HYDROCHLORIDE                                  |   |   |   |                          |   |   |  |  |  |  |  |  |  |  |
| APPL  | APPLICANT FOR DO/EO/US: Sunil Sadanand NADKARNI |   |   |                          |   |   |  |  |  |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: |   |   |   |                          |   |   |  |  |  |  |  |  |  |  |
| 1.  | $\boxtimes$                                     | This is a FIRST submission of items concerning a filing under 35 U.S.C 371.                 |   |                          |   |   |  |  |  |  |  |  |  |  |
| 2.  |   |   | This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.   |                          |   |   |  |  |  |  |  |  |  |  |
| 3.  |   | Ţhis is   | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |                          |   |   |  |  |  |  |  |  |  |  |
| 4.  | $\boxtimes$                                     | The US has been elected by the expiration of 19 months from the priority date (Article 31). |   |                          |   |   |  |  |  |  |  |  |  |  |
| 5.  | $\boxtimes$                                     |   | A copy of the International Application as filed (35 U.S.C. 371 (c)(2)).  |                          |   |   |  |  |  |  |  |  |  |  |
|   | _   | a.  |   |                          | ched hereto (required only if not communicate     | d by the International Bureau             |  |  |  |  |  |  |  |  |
|   |   | b.  | ×   |                          | en communicated by the International Bureau       | •   |  |  |  |  |  |  |  |  |
|   |   | c.  |   |                          | required, as the application was filed with the   | 1   |  |  |  |  |  |  |  |  |
| 6.  |   |   | <br>olish langua  |                          | slation of the International Application as filed | • • • •                                   |  |  |  |  |  |  |  |  |
| •   | _   | a.  |   |                          | ched hereto.                                      | (55 0.0.0. 571 (0)(2)).                   |  |  |  |  |  |  |  |  |
|   |   | ь.  |   |                          | en previously submitted under 35 U.S.C. 154       | (4)(4)                                    |  |  |  |  |  |  |  |  |
| 7.  | $\boxtimes$                                     | -   | _   |                          | s of the International Application under PCT A    |   |  |  |  |  |  |  |  |  |
| ,   | _   | a.  |   |                          | ached hereto (required only if not communica      |   |  |  |  |  |  |  |  |  |
|   |   | b.  |   |                          | peen communicated by the International Burea      | ·   |  |  |  |  |  |  |  |  |
|   |   | c.  |   |                          | not been made; however, the time limit for mal    |   |  |  |  |  |  |  |  |  |
| 7.5   |   | d.  | Ø   |                          | not been made and will not be made.               | king such amendments has NOT expired.     |  |  |  |  |  |  |  |  |
| 8.  |   |   | _   |                          | slation of the amendments to the claims under     | DCT Amiala 10 (25 U.S.C. 271 (a)(2))      |  |  |  |  |  |  |  |  |
| 9.  | ⊠   |   |   |                          | the inventor(s) (35 U.S.C. 371 (c)(4)).           | FC1 Afficie 19 (33 U.S.C. 3/1 (c)(3)).    |  |  |  |  |  |  |  |  |
|   | ⊠   |   |   |                          | ****  | Demonstrated DCT Artists 26 (25 H C C 271 |  |  |  |  |  |  |  |  |
| 10.   | ۵   |   | English language annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).   |                          |   |   |  |  |  |  |  |  |  |  |
| Items   | 11 to 20 b                                      | elow cond   | cern docum  | ent(s) o                 | or information included:                          |   |  |  |  |  |  |  |  |  |
| 11  | <b>.</b>  | I 6   | ation Disale  | Ca                       |   |   |  |  |  |  |  |  |  |  |
| 11.<br>12.  | □.  |   |   |                          | atement under 37 CFR 1.97 and 1.98                | liance with 27 CED 2 20 and 2 21 in       |  |  |  |  |  |  |  |  |
| 12.   |   | include   |   | cument                   | for recording. A separate cover sheet in comp     | liance with 37 CFR 3.28 and 3.31 is       |  |  |  |  |  |  |  |  |
| 13.   |   |   |   | arv ame                  | endment   |   |  |  |  |  |  |  |  |  |
| 14.   |   |   | A FIRST preliminary amendment.  A SECOND or SUBSEQUENT preliminary amendment.   |                          |   |   |  |  |  |  |  |  |  |  |
| 15.   |   |   | A Substitute specification.   |                          |   |   |  |  |  |  |  |  |  |  |
| 16.   |   |   | A change of power of attorney and/or address letter.  |                          |   |   |  |  |  |  |  |  |  |  |
| 17.   |   |   | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.   |                          |   |   |  |  |  |  |  |  |  |  |
| 18.   |   |   | A second copy of the published international application under 35 U.S.C. 154 (d)(4).  |                          |   |   |  |  |  |  |  |  |  |  |
| 19.   |   |   | A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4).  |                          |   |   |  |  |  |  |  |  |  |  |
| 20.   | ⊠   |   |   |                          |   | ppileation 33 0.3.0. 134 (a)(4).          |  |  |  |  |  |  |  |  |
| 20.   |   | Other items or information:  a.   |   |                          |   |   |  |  |  |  |  |  |  |  |
|   |   | a.<br>b.  |   |                          | of Notification of Missing Requirements.          | ₩ G 4004/0417/3 A1.                       |  |  |  |  |  |  |  |  |
|   |   | о.<br>С.  | □<br>⊠  |                          | est for Substitution of Replacement Sheets.       |   |  |  |  |  |  |  |  |  |
|   |   | U.  | لاعا  | reque                    | at for Buostitution of Replacement Sheets.        |   |  |  |  |  |  |  |  |  |

## JC06 Rec'd PCT/PTO 09 MAY 2005

| 10.5. APPLICATION NO. (If known, see 30.65) 8   |  |                     | PCT/IB2003/004998   |                   |                 | ATTORNEY'S DOCKET<br>NUMBER |              |  |  |  |  |
|---|--|---------------------|---|-------------------|-----------------|-----------------------------|--------------|--|--|--|--|
| 21. \(\times\) The follo  | 09825.0001<br>Applicant Use  | Office Use Only     |   |                   |                 |                             |              |  |  |  |  |
| BASIC NATIONA   | \$300.00   | Office Ose Only     |   |                   |                 |                             |              |  |  |  |  |
|   | \$300.00   | \$500.00            |   |                   |                 |                             |              |  |  |  |  |
| National Stage Sea  | rch Fee  | ••••••              | ***************************************                                   | •••••             | \$500.00        |                             | <del> </del> |  |  |  |  |
| National Stage Exa  | \$200.00   | <u> </u>            |   |                   |                 |                             |              |  |  |  |  |
|   | \$1000.00  |                     |   |                   |                 |                             |              |  |  |  |  |
| ☐ Additional fee<br>listing or comp<br>additional 50 s  |  |                     |   |                   |                 |                             |              |  |  |  |  |
| Total Sheets  | E  | xtra Sheets         | Number of additional 50 or fraction thereof (rounded up to a whole number |                   | Rate            |                             |              |  |  |  |  |
| 22 - 100 =  |  | /50=                | x 250.0   |                   | x 250.00        | \$                          |              |  |  |  |  |
|   |  |                     | or declaration later than<br>(37 CFR 1.492 (e)).                          | □ 20              | □ 30            | \$                          |              |  |  |  |  |
| CLAIMS  | NUM  | IBER FILED          | NUMBER EXTRA  | RA                | TE              |                             |              |  |  |  |  |
| Total Claims  | 21   | - 20 =              | 1   | x \$5             | 0.00            | \$50.00                     |              |  |  |  |  |
| Independent Claims  | Claims 3 -3 = 0 x \$200.00   |                     | 0.00  | \$                |                 |                             |              |  |  |  |  |
| ☐ MULTIPLE DEP  | ENDENT (   | CLAIM(S) (if applie | cable)  | +\$36             | 0.00            |                             |              |  |  |  |  |
|   | CULATIONS =  | \$1050.00           |   |                   |                 |                             |              |  |  |  |  |
| ☐ Applicant claim   | s small er   | ntity status. See 3 | 7 CFR 1.27. The fees in   | dicated above are | reduced by 1/2. | \$                          |              |  |  |  |  |
|   | SUBTOTAL =   | \$1050.00           |   |                   |                 |                             |              |  |  |  |  |
| Processing fee of \$ months from the ea   | \$   |                     |   |                   |                 |                             |              |  |  |  |  |
|   |  |                     |   | TOTAL NAT         | TIONAL FEE =    | \$1050.00                   |              |  |  |  |  |
|   |  |                     | CFR 1.21 (h)). The ass<br>). \$40.00 per property.                        | ignment must be a | accompanied by  | \$40.00                     |              |  |  |  |  |
|   | <u>:-</u>  |                     |   | TOTAL FEES        | ENCLOSED =      | \$1090.00                   |              |  |  |  |  |
|   | Amount to be refunded:   | \$                  |   |                   |                 |                             |              |  |  |  |  |
|   |  |                     |   |                   |                 | charged:                    | \$           |  |  |  |  |
|   | a. A check in the amount of \$ 1090.00 to cover the above fees is enclosed.  |                     |   |                   |                 |                             |              |  |  |  |  |
|   | b. Please charge my Deposit Account No in the amount of \$ to cover the above fees.  A duplicate copy of this sheet is enclosed. |                     |   |                   |                 |                             |              |  |  |  |  |
| The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916.</u> A duplicate copy of this sheet is enclosed.                       |  |                     |   |                   |                 |                             |              |  |  |  |  |
| d.  Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |  |                     |   |                   |                 |                             |              |  |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.                    |  |                     |   |                   |                 |                             |              |  |  |  |  |
| SEND ALL CORRESPONDENCE TO:   |  |                     |   |                   |                 |                             |              |  |  |  |  |
| Finnegan, Hende   |  |                     | _   | SIGNATURE         | - Ly            |                             |              |  |  |  |  |
| 901 New York A  |  | -                   |   |                   |                 |                             |              |  |  |  |  |
| Washington, D.C<br>JCP/FPD/sci  | n/25,961<br>ATION NO.  |                     |   |                   |                 |                             |              |  |  |  |  |
| DATED: May 9,   |  |                     |   |                   |                 |                             |              |  |  |  |  |

PCT/IB2003/004998 Sunil Sadanand NADKARNI Attorney Docket No. 09825.0001

## **ANNEXES TO THE**

## PRELIMINARY EXAMINATION REPORT

(ARTICLE 34 AMENDMENTS)

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## REQUEST FOR SUBSTITUTION OF REPLACEMENT SHEETS

Please substitute the attached replacement sheets 14-17 of the claims of the Article 34 Amendments for sheets 14-20 of the claims in the enclosed as-filed PCT application. It is respectfully requested that the claims in the substitute sheets be examined during examination of the patent application. Claims 1-21 are currently pending.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 9, 2005

By: Effect F. Chapman

Reg. No. 25,961

EFC/FPD/sci